

FEB 05 2007

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re. Application Serial No.: 10/760,479 Group Art Unit: 3739
First named inventor: Visram, Naheed Examiner: Vrettakos, Peter J.
Filed on: 01/21/2004
Title: SURGICAL PERFORATION DEVICE WITH ELECTROCARDIOGRAM
(ECG) MONITORING ABILITY AND METHOD OF USING ECG TO
POSITION A SURGICAL PERFORATION DEVICE

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-4450

DECLARATION OF KRISHAN SHAH UNDER 37 CFR 1.132

Sir:

I, Krishan Shah, declare as follows:

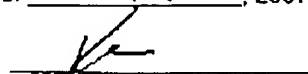
1. I am a named inventor in the above-identified application.
2. I have been active in the cardiology field, and, more specifically, in the field of transseptal procedures, since 1996.
3. The claims of the above-identified application are directed to methods for creating a channel through a cardiac septal material in a body of a patient. These methods use a device, comprising an active electrode, to deliver radiofrequency electrical energy to create the channel. In addition, the active electrode is used to obtain data about an electrical parameter, for example voltage, in order to assess the position of the device.
4. More particularly, the active electrode is used to obtain an electrocardiogram (ECG), or electrogram, signal, which is used to determine the location of the fossa ovalis, which is the desired location for the channel to be created. As disclosed in the application, the fossa ovalis may be located by applying pressure onto the septal tissue and monitoring the resultant ECG signal.
5. I have reviewed the Office Action sent on October 5, 2006 and, in particular, the cited reference to Krishnan (US Patent Application Publication Number 2004/0133113). The apparatus described by Krishnan, for example at paragraph [0080], includes fairly standard-sized electrodes to obtain an intracardiac electrogram, the electrodes being comparable in size (length and diameter) to those found on electrophysiology catheters used for cardiac mapping. Such

electrodes would not be suitable for creating a channel using radiofrequency energy, as described and claimed in the application identified above.

6. In addition, the ECG tracings provided by Krishnan were obtained using "a standard EP deflectable catheter" (paragraph [0057]) and the CARTO system (paragraph [0058]). Appended hereto as Exhibit A is a catalogue page for NaviStar® EP catheters from Biosense Webster® for use with the CARTO system, also from Biosense Webster. These catheters have a diameter of 7 French, or about 2.3 mm, similar to other commercially-available EP mapping catheters.
7. In my opinion, drawing upon my years of experience in this field, it would not have been obvious to a person skilled in the art of transeptal procedures, as of the time the invention was made, to use an active electrode for both creating a channel using RF energy as well as obtaining an ECG signal. In order to create the channel, and as disclosed and claimed in the application identified above, the active electrode should have a diameter of 0.04 cm (0.4 mm) or less. It is well established in the field that an ECG electrode having a larger surface area results in a higher-amplitude signal and, conversely, that an electrode having a smaller surface area results in a lower-amplitude signal. In addition, a physician or technologist, experienced in obtaining intracardiac ECGs and knowledgeable of the state of the art of intracardiac ECG recording, would not consider using such a small electrode to obtain an ECG signal within the heart, due to the difficulty in maintaining sufficient contact with the heart tissue (due to the low surface area) to obtain a satisfactory signal. In other words, using a small electrode substantially increases the likelihood of losing contact between the electrode and the tissue, which in turn introduces artifacts and noise into the system and effectively reduces the signal-to-noise ratio. This would dissuade a person of skill in the art from using such a small electrode for obtaining intracardiac ECGs or electrograms due to a lack of a reasonable expectation of success when using such small electrodes.
8. The invention claimed in the above-identified application was reduced to practice and achieved a surprising and unexpected result; namely, that the ECG signal obtained from the small active electrode was sufficient to ascertain the position of the fossa ovalis.

I, the undersigned, declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Executed this 5 day of Feb., 2007.



Krishan Shah

EXHIBIT A

NAVISTAR® NAVIGATION AND ABLATION CATHETERS

BIOSENSE WEBSTER®

FEB 05 2007



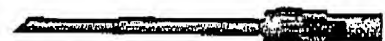
Ideas making a difference

NAVISTAR[®] Temperature Sensing Navigation and Ablation Catheters 7F Quadrapolar with 4 mm Tip/Thermocouple

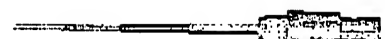
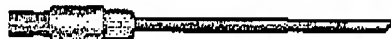
1.74 mm

Hypertronics 25-Pin Connector

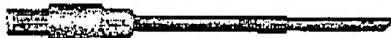
Associated CATHOS CART[™] System Junction Box
Catalog No. C5MHRAM/MHS (Red)
European Order No. 39F-58M



CATHOS[®] System Junction Box to Generator
Catalog No. C70GR10MSTK3 (Stuckart 70 Generator)
European Order No. 39F-43B



Catalog No. C6MPTCM/TCS (Medtronic Atrium[™] 6000-2000)
European Order No. 39F-23B



Now Catalog No.	Made to Order	Old Catalog No.	Tip Electrode	Size	Curve/Color	Spacing	Insertion Length	European Order No.
NS7TCBL174HS		NS7TC-BL-174-HS	4 mm	7F	B-Type/Red	1-7-4 mm	115 cm	34A-15M
NS7TCCL174HS		NS7TC-CL-174-HS	4 mm	8/7F	C-Type/Green	1-7-4 mm	115 cm	34A-25M
NS7TCDL174HS		NS7TC-DL-174-HS	4 mm	7F	D-Type/Blue	1-7-4 mm	115 cm	34A-35M
NS7TCFL174HS		NS7TC-EL-174-HS	4 mm	7F	E-Type/White	1-7-4 mm	115 cm	34A-45M
NS7TCFL174HS		NS7TC-FL-174-HS	4 mm	7F	F-Type/Orange	1-7-4 mm	115 cm	34A-55M
NS7TCJL174HS		NS7TC-JL-174-HS	4 mm	7F	J-Type/Black	1-7-4 mm	115 cm	34A-15M